Golden Oval™ EGGS

December 15, 2004

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203 and 2000N-0504, "Prevention of *Salmonella* Enteriditis in Shell Eggs During Production"

Ladies and Gentlemen:

Thank you for the opportunity to submit these written comments to the Federal Drug and Food Administration (FDA). Golden Oval Eggs is an egg production and processing company with operations in Minnesota and Iowa. We currently have 5,700,000 layers under our ownership and rank in the top ten egg processors in the United States. We are dedicated to providing a safe product to our customers and treat food safety as an extremely important issue within our company.

We note there are twenty-seven (27) instances where you are inviting comment to the docket, but we have limited our comments to the issues which we feel are most important and material to the stated and intended purpose of the proposed regulation. We have reviewed the submitted comments of the United Egg Producers, The Broiler and Egg Association of Minnesota, the Iowa Poultry Association, the State of Minnesota Department of Agriculture in conjunction with the Department of Animal Sciences at the University of Minnesota, amongst others, and take no exception nor have anything to add to or contrary of the comments submitted by the aforementioned. We wholeheartedly support the comments of all industrial representatives who join with us in this effort.

Recognition of Existing Efforts

FDA should recognize that many states and egg production and processing enterprises have already adopted egg quality assurance programs. If such programs are functionally equivalent to FDA requirements, then producers or processors following them should be considered in compliance with FDA's regulations.

00N-0504 C324

Business Office:
340 Dupont Avenue NE, P.O. Box 615
Renville, Minnesota 56284
320-329-8182
320-329-3246 (fax)
Website: www.goldenovaleggs.com

Vaccination

We believe the option of using a vaccination program should be available for producers wishing to pursue such a program. It is our understanding data exists in the US and Europe which demonstrates the effectiveness of vaccination programs. Under a vaccination regimen, we do not believe egg producers should be required to do environmental testing at the 45-week and 22-week time periods but instead would do environmental testing at the time the flock is disposed of (depopulated). We support the written comments of the vaccination companies that we understand will be sent to you on this issue.

Cleaning and Manure Handling

Should an environmental positive be identified, the producer should then pursue a dry cleaning of the building. We do not believe wet cleaning should ever be used due to problems inherent in the process. Wet cleaning can wreak havoc on the metal equipment in a building and can substantially reduce the buildings useful life. Requiring wet cleaning in Northern states in cold seasons would also prove quite problematic.

Wet cleaning has also been shown in some studies to actually increase SE. It would be difficult to comprehend why the agency would propose to use a process that could actually increase the prevalence of SE in a proposed rule it says is necessary to decrease the incidence of the organism.

The handling of the manure will also be problematic and requirements must remain flexible enough to allow the removal of manure only during times when it can be transported and applied to fields in a short period of time. The requirement that all visible manure be removed is unrealistic as some residue will likely remain in porous building materials. While the removal of all manure is a laudable goal, the regulation, must be realistic and practical.

Bio-security

The use of bio-security measures should be specific and tailored to farms and not simply "buildings" in general. Included in this is the issue of clothing and footwear. This should also be farm-specific versus building-specific.

Other Establishments

If food safety related to eggs is truly the purpose of this proposal, then FDA has the responsibility of ensuring all handlers of the eggs or egg products are storing, handling and cooking them in the appropriate manner.

Processing Issues

Egg processing facilities need to be able to recover as much liquid product as is possible from the eggs. If eggs are at too cool a temperature this will not happen. Where the egg product will be pasteurized in processing, FDA should allow the eggs to achieve a warmer temperature prior to processing. FDA should also allow the storage of shell eggs on-farm and prior to processing at temperatures not to exceed 60° for a maximum time period of 5-days prior to processing. This will allow for the potential short-term storage and transportation of the shell eggs to the processing plant and the slow cool down of the shell eggs to maintain shell strength and integrity.

The proposal's requirement that eggs held more than 36 hours be held at 45° F is unnecessary where processing will pasteurize the egg product.

Timing of Testing

The proposal's requirements for implementing testing after the discovery of an environmental positive are too short. If the proposal is to move forward, it should be changed to allow "up to 72-hours" time period between the finding of an environmental positive and the required egg testing. This allows for weekends or holiday weekends when laboratory facilities would most likely not be available to complete the test. In addition, has the agency even determined if lab capacity is adequate for the rule as proposed?

Husbandry Practices

We do not believe FDA has jurisdiction with regard to molting as a husbandry practice. We would suggest the agency review recent research that demonstrates molting has little if any impact on SE shedding from the hens. FDA should rely only on peer-reviewed, duplicative, valid and sound science for making decisions that will affect an entire U.S. industry.

Program Administration

USDA - AMS already inspects egg packing facilities four times per year under the Shell Egg Surveillance Program. If the proposed rule is adopted, the AMS should be in charge of administering this program in since the vast majority of egg producers and processors have long histories of working with this agency and its associated state and federal employees. Utilizing existing resources avoids the diversion of FDA employees from important work like homeland security issues.

Application to All Producers

The current proposal exempts producers with fewer than 3,000 laying hens. However, again, if food safety is the purpose of the proposal, exempting hens based on the size of the operation eviscerates the alleged purpose. It is not the size of laying operation but rather the practices followed that create the safe food we enjoy in this country. To allow smaller producers to avoid food safety simply due to size exposes the entire industry to issues of credibility. Should problems arise, "eggs" are going to be blamed regardless the nature of the operation involved. More importantly, exemptions based on size expose people to food safety issues based on factors unrelated to food safety.

Our comments included in this letter reflect those comments and suggestions made by other egg producers that we have discussed this matter with. We believe the above referenced matters need to be addressed, minimally, and we look forward to the final proposal being in a workable format that best suits the stated intentions of the proposed regulations and accomplishes those objectives in the least intrusive and cost effective manner possible.

Thank you.

Sincerely yours,

Doug Leifermann

Doug Leifermann,
Vice President & CFO

Copy: United Egg Producers
Broiler & Egg Association of Minnesota (BEAM)
Iowa Egg Council/Iowa Poultry Association
Senator Charles Grassley, Iowa
Senator Tom Harkin, Iowa
Senator Mark Dayton, Minnesota
Senator Norm Coleman, Minnesota